

Notice of Allowability

Application No.

10/731,582

Examiner

Michael C. Henry

Applicant(s)

CONNOLLY ET AL.

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to ____.
 2. ☒ The allowed claim(s) is/are 1-20.
 3. ☐ The drawings filed on ____ are accepted by the Examiner.
 4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date ____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____

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EXAMINER'S AMENDMENT/REASONS FOR ALLOWANCE

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brian Buckwalter (Reg # 46,585) on 9/27/04.

The application has been amended as follows:

In claim 1, line 2, the period punctuation "." has been deleted and the period punctuation "." has been added after the given structure (at the end of (Ia)).

In claim 2, the period punctuation "." has been added after the given table.

In claim 3, the period punctuation "." has been added after the given table.

In claim 4, the period punctuation "." has been added after the given table.

Claim 9 (amended). A method of treating a disease caused by the Hepatitis C Virus comprising administering to a patient in need thereof, a therapeutically effective amount of a compound according to claim 1.

In claim 19, line 2, the period punctuation "." has been deleted and the period punctuation "." has been added after the given structure (at the end of (I)).

The following is an examiner's statement of reasons for allowance: The examiner has found claims 1-20 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates to the hemisulfate salt of 1-[4(S)-azido-2(S),3(R)-dihydroxy-4-(hydroxymethyl)-1(R)-cyclopentyl] cytosine, its polymorphic crystalline

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forms and their use for the treatment of disease caused by the Hepatitis C virus. The very relevant prior art documents (WO 02/100415 A2, WO 02/18404 A2, US 5,449,664) to this invention disclose nucleosides including 4'azido nucleosides. However, the hemisulfate salt of l-[4(S)-azido-2(S),3(R)-dihydroxy-4-(hydroxymethyl)-1(R)-cyclopentyl] cytosine much less its polymorphic crystalline forms are not suggested, nor are obvious to those in the prior art. In addition, the nucleosides of the prior art document (US 5,449,664) are not used as antiviral agents.

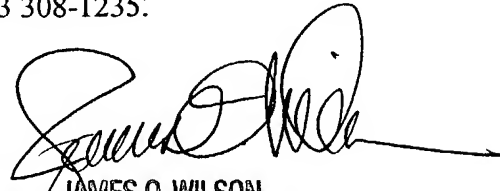
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

September 24, 2004.



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600